



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

1350 104 01-01-027

OCT 28 2004

Mr. Don McFarland
President
McLind Corporation
P.O. Box 3669
Torrance, California 90510-3669

Dear Mr. McFarland:

This is in response to your letters of September 29, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letters state that the following statements will made for the following products:

Lindberg Alpha-Lipoic Acid	"Helps support normal blood sugar levels."
Lindberg Pink Pack Multi-Vitamin and Mineral Packets	"[S]upports healthy blood sugar levels."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood sugar levels; that is, a claim that does not establish that the claims are about blood sugar levels that are already within normal limits implies that the product is intended to treat elevated blood sugar levels (diabetes), which is a disease. Therefore, because the claims you are making for these products represent that the products are intended to affect blood sugar levels but do not also include a statement about them being intended to affect blood sugar levels that are already in the normal ranges, they are implied disease claims.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products

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are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

You also submitted a notification for the product Soy Protein Isolate stating that it would use the claim, among others, "[S]hows that 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce your risk of heart disease." This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between soy protein and risk of heart disease (see 21 CFR 101.82). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between soy protein and heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.82 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.82 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, heart disease.

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert Moore

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

McLind Corporation

Mailing Address: P.O. Box 3669, Torrance, CA 90510-3669
Business Address: 2575 West 237th Street, Torrance, CA 90505

Business: (310) 784-8500

Fax: (310) 784-8528

September 29, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

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Re: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

McLind Corporation, P.O. Box 3669 Torrance, CA 90510-3669, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

"Provides Metabolic & Antioxidant Support**"

"Alpha-Lipoic Acid is often referred to as the metabolic antioxidant because of its involvement in energy producing reactions in the body. Both fat and water soluble, Alpha-Lipoic Acid provides antioxidant protection inside the cell and at the cell membrane level. It also increases antioxidant protection by helping the body recycle Vitamins C and E, CoQ10 and Glutathione. Helps support normal blood sugar levels.*"

These claims are being made for Alpha-Lipoic Acid, which is contained in a product named Lindberg® Alpha-Lipoic Acid Dietary Supplement. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the McLind Corporation and certifies that the information contained in this notice is complete and accurate, and that McLind Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

By:



Don McFarland
President

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McLind Corporation, P.O. Box 3669 Torrance, CA 90510-3669, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

“Healthy Support for: Bones and Joints* - Breast Health* - Blood Sugar Balance* - Hair, Skin and Nails* - Heart and Circulation* - Immune Function* - Urinary Tract* - Vision and Eye Health* - Overall Health*”

“Designed to fight the effects of aging*”

“Vitamin B Complex. Includes a full array of B vitamins. They are vital for energy production, heart and prenatal health.*”

“Calcium and Boron. You’ll receive a full 100% RDI of calcium from three sources along with the mineral, boron, to support bone health.*”

“Minerals. Provides all the bone support minerals critical to women. Includes the optimal intake level of selenium shown in the latest research.*”

“Lutein. This natural, antioxidant carotenoid, found in high concentrations in the macula, supports eye health.*”

“Lycopene. Known as the red carotenoid in tomato, it may support overall health including breast health.*”

“Alpha Lipoic Acid. Provides antioxidant protection inside the cell and extends the life of vitamins C and E.*”

“Grape Seed Extract. An excellent source of OPCs, antioxidants which benefit the cardiovascular system.*”

“Cranberry. The natural, concentrated fruit constituents found in cranberry support a healthy urinary tract.*”

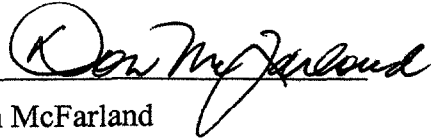
“Bioflavonoids. From citrus, these compounds support vein and capillary health.*”

“Chromium. We use a patented, niacin-bound form of chromium which supports healthy blood sugar levels.*”

“Silica and MSM (biological sulfur). These minerals are important for beautiful hair, nails and skin.*”

These claims are being made for a product named Lindberg® Pink Pack® Multi-Vitamin and Mineral Packets. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the McLind Corporation and certifies that the information contained in this notice is complete and accurate, and that McLind Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

By: 
Don McFarland
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